IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 06-230 (GMS)
v.	)	
	)	
APOTEX, INC.,	)	
	)	
Defendant.	)	

APOTEX INC.'S REPLY IN SUPPORT OF
ITS MOTION FOR LEAVE TO FILE SURREPLY

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Dated: October 20, 2006
756815/20234

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES AND RULES

OTHER AUTHORITIES

INTRODUCTION

Defendant Apotex, Inc. ("Defendant" or "Apotex") replies as follows to Plaintiff Merck & Co., Inc.'s ("Plaintiff's" or "Merck's") opposition to Apotex's motion for leave to file a surreply. First, Apotex's surreply was not improper. It was filed to (1) address an argument Merck raised in its reply that should have been included in its opening brief and which Apotex could not reasonably have anticipated in responding to Merck's motion, and (2) to bring to the Court's attention certain recent developments in the United States Supreme Court that bear on this case.

Apotex is well aware of this Court's heavy caseload and in no way wishes to burden the Court by rehashing arguments or raising minor points. However, the stakes in this case are very high in that Apotex stands to lose millions of dollars if it is blocked from entering the market for generic alendronate sodium on February 6, 2008. Moreover, Apotex's injury is particularly unjust because its generic version clearly does not infringe any valid patent held by Merck as evidenced by Merck's admissions in the covenant not to sue. The Court should therefore use its discretion and allow Apotex's surreply.

ARGUMENT

I. APOTEX'S SURREPLY IS PROPER

Contrary to Merck's assertion, there is nothing in the local rules that prohibits the filing of a surreply. Local Rule 7.1.2(c) merely requires leave of court prior to filing additional papers in support of a motion. Apotex has sought leave by way of the instant motion.

Moreover, Merck should have raised its collateral consequences argument in its opening brief. Merck is contending that the covenant not to sue has rendered this case

moot. As Apotex mentioned in its response brief, Merck has the burden of establishing mootness. To satisfy its burden Merck should have shown in its opening brief that no exception to mootness applies, including that there are no collateral consequences resulting from the Court's dismissal without a decision on the merits. Merck failed to even recognize that it had the burden of proof to show that this case was moot, much less satisfy that burden in its opening brief, and it raised its argument improperly for the first time in its reply brief.

Furthermore, it is within the Court's discretion to grant Apotex leave to file a surreply. Apotex's surreply is warranted because Apotex could not have anticipated all the arguments raised in Merck's reply as to why the collateral consequences doctrine did not apply. Merck asserted for the first time in its reply brief that the collateral consequences doctrine did not apply because the collateral injury to Apotex was not caused by Merck's lawsuit, but rather is a product of the statutory scheme under Hatch-Waxman. That argument is wrong because Merck filed suit and then sought dismissal based upon a covenant not to sue Apotex. Those actions directly resulted in: (1) a 30 month stay of the FDA's approval of Apotex's ANDA; and (2) avoidance of a court decision triggering event if this case is dismissed without any findings on infringement or validity. Apotex's response focused mainly on the harm caused by Merck's avoidance of a court decision that would trigger the first generic applicant's 180-day exclusivity period. In its surreply, Apotex focused on the harm caused by the 30-month stay. The timing of the two is about the same if the first generic filer enters the market on February 6, 2008 when Merck's exclusivity on the main ingredient patent expires. However, contrary to Merck's argument, the 30-month stay would not be imposed but for Merck's

filing of suit. In other words, Merck took advantage of a court proceeding to obtain a 30-month stay from the FDA.

With regard to the developments in the Supreme Court regarding the *Apotex v. Pfizer* case, *i.e.*, Pfizer's suggestion of mootness, occurred after Apotex filed its response. In its earlier response, Apotex mentioned that the Supreme Court was considering Apotex's petition for certiorari in that case and had sought the Solicitor General's views on the matter. Since the *Apotex v. Pfizer* case could have impacted the present case if certiorari had been granted, Apotex deemed it appropriate to bring the developments in that case to this Court's attention. Merck's suggestion that this somehow violated the local rules is without merit.

II. THE 30 MONTH STAY WILL LIKELY REMAIN IN EFFECT IF THIS CASE IS DISMISSED FOR LACK OF SUBJECT MATTER JURISDICTION

Merck contends that the collateral consequences doctrine does not apply because the 30-month stay will terminate following a dismissal with prejudice based upon Merck's covenant not to sue. The only authority Merck cites for this proposition is the statute itself, 21 U.S.C. § 355(j)(5)(B)(iii) (2003), specifically the parenthetical referring to a "substantive determination that there is no cause of action for patent infringement or invalidity."

As noted by Merck, the parenthetical in the statute was added as a result of the Medicare Amendments Act in 2003. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1101(a)(2)(A)(ii), 117 Stat. 2066 (amended 2003) (hereinafter "MMA"). Previously, the statute provided, in relevant part, that: "approval shall be made effective upon the expiration of the thirty-month period

beginning on the date of the receipt of the [paragraph IV] notice...except that (I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision..." 21 U.S.C. § 355(j)(5)(B)(iii) (2002). The MMA added the parenthetical: "including any substantive determination that there is no cause of action for patent infringement or invalidity." 21 U.S.C. § 355(j)(5)(B)(iii) (2003).

Apotex is not aware of any ruling by the FDA in which it has construed the parenthetical Merck contends offers Apotex relief. Indeed, it seems illogical that the 30-month stay would remain in effect if this Court were to grant Merck's motion to dismiss. However, there is no guarantee that the FDA would construe the statute as Merck suggests. Since the FDA has not construed the language in the parenthetical, and it is their job to do so,[1] Apotex remains at risk that the FDA will construe the language such that a dismissal for lack of subject matter jurisdiction will not terminate the 30-month stay. Thus, there remains an actual and concrete controversy.

In order for Merck to satisfy its burden of establishing mootness, Merck should seek a ruling from the FDA regarding the meaning of the language in the parenthetical. If Merck's suggested interpretation is correct and a dismissal for lack of subject matter jurisdiction terminates the 30-month stay, that would remove one of the collateral harms asserted by Apotex. Apotex also faces the collateral injury due to being denied an

[1] *See generally Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.D.C. 2006) (upholding FDA's decision finding that dismissal for lack of subject matter jurisdiction did not qualify as a "court decision" sufficient to trigger the 180-day exclusivity period); *see also Minn. Mining and Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 783 n. 4 (Fed. Cir. 2002) (holding that the district court did not err in failing to order that a grant of summary judgment would not trigger the 180-day exclusivity period since "[s]uch an order would...constitute improper judicial enforcement of the provisions of the Hatch-Waxman Amendments, outside of the context of an [Administrative Procedure Act] suit.").

opportunity to obtain a court decision on the merits that would trigger the first generic applicant's 180-day exclusivity period.

In any event, the risk that the FDA may not interpret the language in the parenthetical as Merck suggests is very real. The FDA considered, but withdrew, a rule that explicitly would have terminated the 30-month stay if the case was dismissed without a court decision on the merits. The FDA's proposed rule § 314.107(g) provided in relevant part:

> (g) *Effect of dismissal of litigation on 30-month stay.* If the patent litigation between the ANDA applicant and the patent owner or NDA holder described in paragraph (b)(3)(A) of this section is dismissed without a court decision on the merits of the patent claim, whether the dismissal is with or without prejudice, the agency may immediately approve the ANDA that was the subject of the litigation, if it is otherwise eligible for approval.

180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42873, 42886 (1999) (to be codified at 21 C.F.R. pt. 314) (proposed Aug. 6, 1999). On November 1, 2002, however, the FDA withdrew the proposed rule published on August 6, 1999, without commenting on the provision regarding the effect of dismissal on the 30-month stay. *See* 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 67 Fed. Reg. 66593 (2002) (to be codified at 21 C.F.R. pt. 314) (withdrawal of proposed rule). Apotex was unable to find any subsequent rule proposed by the FDA that incorporated something similar to the proposed § 314.107(g). The current version of 21 C.F.R. § 314.107 provides that: "If before the expiration of the 30-month period…the court issues a final order that the patent is invalid, unenforceable, or not infringed, approval may be made effective on the date the court enters judgment." 21 C.F.R. § 314.107(b)(3)(ii). There is nothing in the current version of the FDA's

regulations that mandates approval if an infringement action is dismissed based upon a covenant not to sue with no court findings of noninfringement or invalidity. If the FDA thought that the parenthetical added by the MMA included a dismissal without a decision on the merits, as Merck suggests, one would think that the FDA would attempt to amend its rule by proposing something similar to the former proposed § 314.107(g). But the FDA has not attempted to do so. Thus, as it stands now, it is at best unclear whether a dismissal based upon a covenant not to sue would terminate the 30-month stay.

Even if Merck is correct about the effect of a dismissal on the 30-month stay, the Court should not place Apotex in the same position it was in before Merck filed this suit by dismissing this case. Merck filed suit and is now attempting to manipulate the Court's jurisdiction so it can avoid an adverse judgment. It is Merck who is attempting to game the system in this way, not Apotex.

There is a real and concrete controversy here regarding the validity and infringement of Merck's patents as demonstrated by Merck's covenant not to sue, which admits that the relevant claims in one of the patents were held invalid and that the products that are the subject of Apotex's ANDA do not contain one or more of the claim elements in the other patents, yet refuses to admit noninfringement or invalidity. Apotex is entitled to a judgment on the merits so it can market its noninfringing generic version of alendronate sodium on February 6, 2008, when Merck's exclusivity on the main ingredient patent expires.

There is nothing in the Hatch-Waxman scheme that prohibits a secondary generic from triggering the 180-day exclusivity period prior to when the first generic filer(s) is able to enter the market. To the contrary, it is well established that the "court decision"

triggering event can be generated in a lawsuit with any generic filer, not just the first generic filer(s). *See SmithKline Beecham Corp. v. Geneva Pharms., Inc.*, 210 F.R.D. 547, 554 (E.D. Pa. 2002) (denying first generic filer's attempt to intervene in case to prevent court decision that might have triggered its 180-day exclusivity before it could enter the market; "it is clear that [the first generic filer's] exclusivity period can be triggered by the termination of an action commenced by a subsequent applicant"); *Minn. Mining and Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 780 (Fed. Cir. 2002); *Teva Pharms., USA, Inc. v. FDA*, 182 F.3d 1003, 1005 n. 3 (D.D.C. 1999) ("As interpreted by the FDA, the statute does not guarantee the first ANDA applicant a 180-day period of exclusivity. The court-decision trigger can be activated by any subsequent ANDA applicant's litigation whether or not the first applicant has enjoyed a period of exclusivity."); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1073 (D.D.C. 1998) (suggesting use of declaratory judgment action as means for subsequent ANDA applicant to trigger exclusivity period).

If Congress wanted to protect the first generic filer's 180-day exclusivity period from being triggered in a different action before the first generic could utilize the exclusivity period, it certainly could have amended the statute to do just that. It has not, and Apotex has every right to a decision on the merits that, if in Apotex's favor, would constitute a triggering event of the first generic filer's 180-day exclusivity period. Allowing Apotex to enter the market in this way is consistent with the overall purpose of the Hatch-Waxman Amendments, *i.e.*, to make it easier for generic drugs to enter the market by allowing challenges to invalid and non-infringed patents that would otherwise block the public's access to generic drugs.

Moreover, Merck's concern that Apotex is attempting to scheme the system by usurping Barr Laboratories, Inc.'s ("Barr's") and Teva Pharmaceuticals USA, Inc.'s ("Teva's") rights to the 180-day exclusivity period is disingenuous to say the least. To the contrary, Merck is desperately attempting to keep even Barr and Teva out of the market for as long as possible.

Earlier this year, Merck filed a complaint in this court against Teva seeking to reopen the judgment in C.A. No. 01-048 (JJF) (D. Del.) that held two claims of Merck's '329 patent invalid. *See Merck & Co., Inc. v. Teva Pharms. USA Inc.*, C.A. No. 06-310 (GMS) (D. Del.). The '329 patent would have protected Merck's monopoly on alendronate sodium until at least 2018. In its complaint, Merck alleged that the prior judgment of invalidity was a result of Teva's fraud, misrepresentations, or other misconduct. Teva moved to dismiss and also filed a motion for sanctions under Rule 11 of the Federal Rules of Civil Procedure. In response, Merck dismissed its complaint. Merck's filing of that extraordinary and baseless action against Teva demonstrates how far Merck will go to protect its monopoly against generic competition.

More recently, Merck filed a complaint with the United States International Trade Commission in its latest attempt to protect its Fosamax® drug from generic competition. In that action, Merck complained that the Indian generics firm Cipla, Ltd. ("Cipla"), one of Teva's alleged suppliers, is violating one of Merck's process patents for alendronate sodium by exporting alendronate salts and alendronate sodium tablets for sale in the U.S. *See In the Matter of Certain Alendronate Salts and Products Containing Same*, Inv. No. 337-TA-584 (attached hereto as Exhibit A). An ITC ruling in Merck's favor could delay

generic launch by generic companies, such as Teva, that have supply agreements with Cipla, or could force those companies to find other suppliers.

Merck also sued Teva and Barr in June 2006 for a declaratory judgment that Teva's and Barr's "anticipated" sale of alendronate sodium (that would not occur until February 6, 2008 at the earliest) infringed a number of Merck's process patents for alendronate sodium, including the one that was alleged in the ITC action. *See Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, C.A. No. 2:06-cv-2484 (D.N.J.) and *Merck & Co., Inc. v. Barr Labs., Inc.*, C.A. No. 2:06-cv-2486 (D.N.J.). If Merck is successful in those actions, it would be able to delay generic entry until 2009.

In addition to delaying the entry by the first generic filers, Merck also wants to limit the number of generic competitors during the first 180 days after generic entry to keep prices higher than they would be otherwise and also so that it can introduce its own generic version in order to maintain as large a market share as possible. Thus, Merck's concern that the 180-day exclusivity period not be triggered before Teva and Barr are able to enter the market is based upon Merck's own interest in maintaining prices and market share, not Teva's and Barr's rights.

III. THE FEDERAL CIRCUIT'S "REASONABLE APPREHENSION" TEST REMAINS PENDING BEFORE THE UNITED STATES SUPREME COURT

Merck contends that the Supreme Court's denial of Apotex's petition for certiorari in *Apotex v. Pfizer* supports its position that there is no case or controversy in the present action. That is wrong. The Supreme Court receives thousands of petitions for certiorari and so necessarily must deny the vast majority. Thus, it is hard to read anything

into the Supreme Court's denial of a petition for certiorari.[2] If the Supreme Court had granted Apotex's petition, a ruling in that case may have been helpful in deciding this case. However, nothing should be inferred from the Supreme Court's denial of Apotex's petition.

Moreover, to the extent that Merck suggests that the Federal Circuit's "reasonable apprehension" test will remain intact now that the Supreme Court has denied Apotex's petition in *Apotex v. Pfizer*, Merck is wrong. The Supreme Court recently heard oral argument in *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958 (Fed. Cir. 2005), *cert. granted*, 126 S. Ct. 1329, 74 U.S.L.W. 3457 (U.S. Feb. 21, 2006) (No. 05-608), which also dealt with the Federal Circuit's "reasonable apprehension" test.

The comments made by the justices during oral argument lead one to the conclusion that the Court is likely to reject the Federal Circuit's "reasonable apprehension" test. During oral argument, the following comments were made by Justice Breyer and Justice Souter regarding the Federal Circuit's "reasonable apprehension" test:

> Justice Breyer: Shouldn't we send that back? I mean, I thought we were here to decide one question, that the Federal Circuit has said that unless there is a reasonable apprehension of a lawsuit, you can't bring a declaratory judgment action because of the Constitution of the United States. *Now I have to admit, I looked up, or I had my law clerk look up probably now hundreds of cases, and we can't find in any case such a requirement.* Indeed, the very purpose, as we just heard the SG say of this act, the declaratory judgment act, seems to be to allow people who do a contract, who are in a real concrete disagreement, to get a declaratory judgment without getting rid of the contract. But I might be wrong about that. (Oral Argument Transcript at pp. 27-28) (emphasis added).
>
> Justice Souter: I've never ever seen anywhere it said that there also has to be a reasonable apprehension of a lawsuit in the absence of the

[2] Apotex noted in its surreply that Pfizer's suggestion of mootness was based not only on its presentation of a covenant not to sue on Apotex but also on the fact that Teva Pharmaceuticals Industries Ltd. (the first generic filer) had recently entered the market with a generic version of the drug at issue. *See* Apotex's Surreply at pp. 6-7.

> declaratory judgment. I just never found that phrase and I can't imagine why it would be part of the law....I'm just wondering if there is an additional reason that there has to be a reasonable apprehension of a lawsuit in the absence of the declaratory judgment action. It's that phrase that I've never found anywhere and can't think of any reason why that would be an additional constitutional requirement..." (Oral Argument Transcript at p. 43.)

Although it is difficult to predict the Court's decision on the basis of oral argument, it is telling that the only two justices that commented on the "reasonable apprehension" test both mentioned that there was no support in the Supreme Court's jurisprudence for such a test.

Merck's motion to dismiss was based solely on cases applying the Federal Circuit's "reasonable apprehension" test. *See, e.g., Super Sack v. Chase*, 57 F.3d 1054, 1059 (Fed. Cir. 1995). If the Supreme Court overturns the Federal Circuit's "reasonable apprehension" test, then there is no basis for Merck's motion and it should be denied. Because the Supreme Court's decision in *MedImmune* is likely to be dispositive of Merck's motion to dismiss, at a minimum, this Court should wait for the ruling in *MedImmune* before deciding Merck's motion and let the case proceed.

CONCLUSION

For the foregoing reasons, Apotex respectfully requests that the Court grant leave for Apotex to file its surreply.

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Dated: October 20, 2006
756815/20234

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on October 20, 2006, the attached document was hand delivered on the following person and was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

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August 22, 2006

DOCKET NUMBER 2500
Office of the Secretary
Int'l Trade Commission

VIA HAND DELIVERY
The Honorable Marilyn R. Abbott
Secretary
U.S. International Trade Commission
500 E Street, S.W., Room 112
Washington, DC 20436

Re: CERTAIN ALENDRONATE SALTS AND PRODUCTS CONTAINING SAME

Dear Secretary Abbott:

Enclosed for filing on behalf of Merck & Co., Inc. ("Merck") are the following documents in support of Merck's request that the Commission institute an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended. A request for confidential treatment for Confidential Exhibits 4, 5, 6, 24, 25 and 26 to the Complaint is included with this filing.

Accordingly, Merck submits the following documents:

1. An original and twelve (12) copies of Merck's verified Complaint (original and one copy unbound, without tabs (Rules 201.6(c), 201.4(f)(3)(i), and 210.8(a));

2. An original and six (6) copies of the confidential and non-confidential exhibits to the Complaint (original and one copy unbound, without tabs). Please note that Confidential Exhibits 4, 5, 6, 24, 25, and 26 have been segregated from the other exhibits and are accompanied by a request for confidential treatment (Rules 201.6(c), 201.4(f)(3)(i) and 210.8(a));

3. One (1) additional copy of the Complaint and accompanying exhibits, for service upon the one proposed respondent (Rules 210.4(f)(3)(i), and 210.8(a));

4. One (1) additional copy of the Complaint and accompanying non-confidential exhibits for service upon the government of India;

5. A certified copy of the United States Patent No. 4,922,007 (the "'007 patent") (Rule 210.12(a)(9)(i));

6. An original and three (3) copies of the certified copy of the assignment of the '007 patent (Rule 210.12(a)(9)(ii));

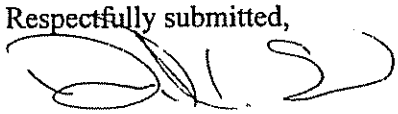
7. An original and three (3) copies of the certified prosecution history of the '007 patent (Rule 210.12(c)(2));

8. Four (4) copies of each reference document mentioned in the prosecution history of the '007 patent (Rule 210.12(c)(3)); and

9. A letter and certification pursuant to Commission Rules 210.6(b) and 210.5(d) requesting confidential treatment of Confidential Exhibits 4, 5, 6, 24, 25, and 26.

Thank you for your attention to this matter. Please contact us if there are any questions pertaining to this submission.

Respectfully submitted,



David N. Southard

Counsel for Complainant
Merck & Co., Inc.

Enclosures

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of	)	Investigation
	)	No. _____
CERTAIN ALENDRONATE SALTS AND PRODUCTS CONTAINING SAME	)	

COMPLAINT OF MERCK & CO., INC.
UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED

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TABLE OF CONTENTS

TABLE OF EXHIBITS

1) U.S. Patent No. 4,922,007

2) Assignment for the '007 patent

3) MERCK & Co., Inc.'s Annual Report for 2005

4) **CONFIDENTIAL:** Estimated Cost and Square Footage of MERCK Facilities Where FOSAMAX® Tablets Are Formulated and Packaged

5) **CONFIDENTIAL:** Representative List and Cost of Equipment Used at MERCK Facilities Where FOSAMAX® Tablets Are Formulated and Packaged

6) **CONFIDENTIAL:** Approximate Number of MERCK Employees Involved in the Formulation, Packaging and Distribution of the Drug FOSAMAX®

7) Sixty-Ninth Annual Report for 2004-2005 for CIPLA LTD

8) Piyush Kheria, *A Pipeline Story - Exploring Valuations*, envestmentz.com, January 8, 2002

9) Press Release Entitled, *The Third Express Pharma Pulse Awards* from www.cipla.com/whatsnew/ciplanews.htm

10) Results of U.S. Drug Master File Search for DMF No. 14335

11) *Cipla 4QFY03 Results Update* from Inquire™ Indian Equity Research by Motilal Oswal™

12) Chemo Dynamics, L.P. Analytical Report Re: Analysis of Cipla Alendronate Tablets ("OSTEOFOS")

13) Declaration of Barry Horvick

14) *Osteoporosis Overview*, May 2006, from www.niams.nih.gov/bone/hi/overview.htm

15) Listing of CIPLA Manufacturing Facilities from www.cipla.com/corporateprofile/facilities.htm

16) OSTEOFOS Product Description from www.cipla.com/admin.php?mode=prod&action=disp&id=334

17) (A) Global Presence from http://www.cipla.com/globalpresence/globalpresence.htm

(B) Bulk Drugs, Active Pharmaceutical Ingredients from www.cipla.com/ourproducts/bulkdrugs/api.htm

18) Chart of Foreign Patents and Foreign Patent Applications Corresponding to the '007 Patent

19) Interview with Yusuf K. Hamied, Chairman and Managing Director of CIPLA from www.cipla.com/whatsnew/news.htm

20) Teva Pharmaceuticals USA, Inc.'s Answer and Counterclaim, July 21, 2006, *Merck & Co., Inc. v. Teva Pharmaceuticals, USA, Inc.*, Civil Action No. 06-2484 (WHW), (D.N.J.)

21) Claim Chart Showing Proposed Respondent's Infringement of the '007 Patent

22) Letter from MERCK to CIPLA, dated April 3, 2006.

23) Photocopies of MERCK's Once Weekly FOSAMAX® tablets

24) **CONFIDENTIAL:** Supply Chain Map for FOSAMAX® Tablets

25) **CONFIDENTIAL:** *NDA 20-560: FOSAMAX (Alendronate Sodium) Tablets Pre-NDA Submission of Control and Manufacturing Data*, MERCK Research Laboratories, Vol. 1.1 (Dec. 29, 1994)

26) **CONFIDENTIAL:** Claim Chart Showing MERCK's Practice of the '007 Patent

I. INTRODUCTION

1.1 Complainant MERCK & CO., INC. ("MERCK" or "Complainant") requests that the United States International Trade Commission commence an investigation, pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337(a)(1)(B), to remedy the unlawful importation into the United States, the sale for importation into the United States, and/or the sale within the United States after importation of certain alendronate salts and products containing same that are made, produced, or processed by means of a process covered by the claims of valid and enforceable United States Patent No. 4,922,007 owned by MERCK ("the '007 patent").

1.2 The proposed respondent CIPLA LTD. ("CIPLA" or "Proposed Respondent") has engaged in unlawful activities in violation of Section 337 through the importation into the United States, the sale for importation into the United States, and/or the sale within the United States after importation of certain alendronate salts and products containing same that are made, produced, or processed by means of a process covered by the claims of the '007 patent. Additionally, the importation, sale for importation, and/or sale after importation, of products containing CIPLA's bulk alendronate is imminent.

1.3 MERCK owns, by assignment, the entire right, title and interest in and to the '007 patent. A copy of the '007 patent is attached to this Complaint as **Exhibit 1**. A copy of the recorded assignment of the '007 patent accompanies this Complaint as **Exhibit 2**. Pursuant to Commission Rule 210.12(a)(9)(i) and (ii), a certified copy of the patent and the assignment also accompany this Complaint.

1.4 As required by Section 337(a)(2) and defined by Section 337(a)(3), an industry in the United States exists relating to certain alendronate salts and/or products containing same protected by the '007 patent. The process claimed in the '007 patent is used by MERCK to manufacture alendronate sodium, the active ingredient in MERCK's FOSAMAX® tablets, which are sold by MERCK in the United States. The domestic industry for the '007 patent

includes MERCK's significant United States investments and expenditures in the production, formulation, packaging and distribution of alendronate as FOSAMAX® tablets, in addition to Merck's significant employment of labor in the United States to produce FOSAMAX® tablets and its substantial investments in the exploitation of the '007 patent.

1.5 MERCK seeks a permanent limited exclusion order, pursuant to Section 337(d)(2), prohibiting from entry into the United States alendronate salts manufactured by CIPLA, and products containing such alendronate salts, for the life of the '007 patent.

1.6 MERCK also seeks a permanent cease-and-desist order pursuant to Section 337(f), prohibiting CIPLA from marketing, demonstrating, distributing, offering for sale, selling, or otherwise transferring, including the movement or shipment of inventory, in the United States any imported alendronate salts or products containing such alendronate salts, that infringe one or more claims of the '007 patent.

II. COMPLAINANT

2.1 Complainant MERCK is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889. MERCK is a leading research-driven pharmaceutical products and services company. MERCK discovers, develops, manufactures and markets a broad range of innovative products to improve human and animal health, directly and through joint ventures. MERCK has distinguished itself as one of the world's leading pharmaceutical companies and one of the largest drug manufacturers in the United States. In addition to FOSAMAX® tablets, MERCK has developed and marketed many important and innovative pharmaceutical products, including ZOCOR®, PEPCID® and SINGULAIR® tablets. MERCK is also heavily involved in public health and outreach initiatives at local and international levels. Among its initiatives, MERCK is committed to improving access to life saving medicines for diseases such as AIDS and River Blindness in developing countries. A copy of MERCK's 2005 annual report accompanies this Complaint as **Exhibit 3**.

2.2 MERCK developed FOSAMAX® tablets, which are approved for use in the prevention and treatment of osteoporosis[1] and Paget's disease.[2] The active ingredient in FOSAMAX® tablets is a sodium salt of alendronate, 4-amino-1-hydroxybutylidene bisphosphonic acid monosodium salt trihydrate, also known as alendronate sodium or "alendronate." In 1994, MERCK filed a New Drug Application ("NDA") with the Food and Drug Administration ("FDA") seeking approval to market FOSAMAX® tablets. The FDA approved MERCK's marketing of alendronate sodium tablets in 1995. MERCK now carries out substantial activities in the United States relating to its alendronate product – FOSAMAX® tablets. In particular, MERCK maintains facilities in the United States where MERCK produces and formulates FOSAMAX® tablets from the alendronate it manufactures abroad according to the process claimed in the asserted patent. MERCK has a significant number of employees in the United States involved in the production and distribution of FOSAMAX® tablets. *See* **Confidential Exhibits 4-6.**

2.3 MERCK sought and obtained patent protection in the United States for a number of inventions relating to alendronate, including the process for manufacturing alendronate sodium as claimed in the '007 patent.[3] MERCK is currently asserting the '007 patent and its other alendronate patents against generic companies who have filed Abbreviated New Drug Applications ("ANDA") with the FDA for generic forms of FOSAMAX® tablets. *See* **Section**

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1 Osteoporosis is a generalized, progressive loss of bone tissue leading to an increased risk of bone fracture.

2 Paget's disease is a chronic disorder of the skeleton in which areas of bone grow abnormally, enlarging and becoming soft, making these sections of bone weaker and more likely to break then other areas of the bone.

3 MERCK has several product patents that relate to alendronate, including U.S. Patent No. 4,621,077 ("the '077 patent") for any use of FOSAMAX® tablets to inhibit bone resorption, and U.S. Patent No. 5,994,329 for the once-weekly use of FOSAMAX® tablets. MERCK owns several other patents claiming processes for manufacturing FOSAMAX® tablets, including U.S. Patent Nos. 5,159,108, 5,019,651, 5,510,517, 5,648,491. MERCK is not asserting these patents in this Complaint.

X. ANDAs are "abbreviated" because they rely upon the safety and efficacy data that the innovator drug company submitted in support of its NDA. In this way, ANDAs frequently allow a generic drug company to enjoy a simpler and faster approval process for entry into the United States market.

III. PROPOSED RESPONDENT

3.1 Proposed Respondent CIPLA is an entity organized and existing under the laws of India. CIPLA maintains legal and administrative headquarters at Mumbai Central, Mumbai 400 008, India.[4] A copy of CIPLA's Sixty-Ninth Annual Report for 2004-2005 is attached hereto as **Exhibit 7**.

3.2 CIPLA manufactures and exports bulk drugs and formulations. Instead of investing in research and development and high risk ventures, CIPLA has a history of filing Drug Master Files ("DMF")[5] with the FDA. *See* **Exhibit 8** at 12. By filing a DMF, CIPLA is able to form alliances with ANDA holders in the United States, to supply ANDA holders with pharmaceutical ingredients covered by the DMF, and to participate in the generic drug market. *Id.* at 14. This strategy allows CIPLA to make substantial revenue in the generic drug market in the United States without the expense or risk associated with filing an ANDA or spending capital on research and development. *Id.* CIPLA touts this partnering strategy in news articles posted on its website, emphasizing that it has "entered into a string of supply contracts with generic companies in the U.S.," and that the "bulk of [its] export sales comes from the U.S. and Europe." **Exhibit 9** at 2.

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4 Mumbai was formerly known as Bombay.

5 A DMF is a submission to the FDA that provides confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of human drugs. A generic drug company's ANDA may rely upon the contents of a DMF. *See* 21 C.F.R. § 314.420. The FDA reviews a DMF when another FDA filing (e.g., an ANDA) relies upon it.

3.3 CIPLA filed a DMF for alendronate salts with the FDA. *See* **Exhibit 8** at 14 and **Exhibit 10**. Upon information and belief, CIPLA has entered into agreements to supply alendronate salts in tablet or bulk form to generic companies for the United States market. *See* **Exhibit 11** at 3. Upon information and belief, CIPLA's alendronate salts are made, produced, or processed by means of a process claimed in the '007 patent. *See* **Exhibit 12**. CIPLA then imports into the United States, sells for importation into the United States, and/or sells within the United States after importation the infringing products. *See* **Exhibit 13** and **Section VI**.

3.4 MERCK is aware of several other companies, in addition to CIPLA, that have filed DMFs with the FDA for alendronate sodium.[6]

3.5 CIPLA also manufactures and sells alendronate sodium tablets under the trade name OSTEOFOS. CIPLA imports, sells for importation into the United States, or sells after importation into the United States OSTEOFOS tablets. *See* **Section VI**. OSTEOFOS has been purchased in the United States from no less than five Internet pharmacies. *See* **Section VI**.

IV. THE PRODUCTS AT ISSUE

4.1 The articles involved in this investigation are certain alendronate salts, including alendronate sodium in powder or tablet form, and products containing such salts.

4.2 Alendronate sodium is the active ingredient in MERCK's FOSAMAX® tablets for the treatment of osteoporosis and Paget's disease. Osteoporosis is a widespread condition and constitutes a major health concern in industrialized countries, especially for women, older people, smokers, and people of European and Asian descent. Osteoporosis is often characterized by vertebral collapse (with associated increased spinal curvature, loss of height and backache), and by wrist and hip fractures that occur with little or no trauma. Over 10 million individuals in

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6 The DMF holders other than CIPLA about which MERCK is aware are Brantford Chemicals Inc., Alchymars SpA, Chemi SpA, Signa SA De CV, Medichem SA, Pharmaceutical Works Polpharma, Teva Pharmaceuticals and Shijiazhuang Pharmaceutical Group. As of the filing of this Complaint, MERCK has not been able to determine whether these DMF holders are currently importing bulk alendronate into the United States.

the United States have osteoporosis and almost 34 million more have low bone mass, placing them at increased risk for osteoporosis. **Exhibit 14** at 1. FOSAMAX® tablets are also prescribed for the prevention of osteoporosis because they have been shown to reduce the chance of fractures, including those of the spine and hip.

4.3 CIPLA manufactures certain alendronate salts and products containing such salts outside the United States. Specifically, CIPLA manufactures and sells alendronate sodium in tablet form under the trade name OSTEOFOS, and manufactures and sells alendronate sodium in bulk form for export. CIPLA's website shows that its manufacturing facilities are located in India, *see* **Exhibit 15**, and the listed subject of CIPLA's DMF shows that its alendronate salts are produced in India, *see* **Exhibit 10**. Information obtained in discovery may also reveal additional trade names for other alendronate products manufactured by CIPLA which infringe the asserted patent.

4.4 CIPLA's alendronate salts and products containing such salts, including OSTEOFOS, are imported into the United States, sold for importation into the United States, or sold within the United States after importation. *See* **Exhibit 13.** Upon information and belief, those alendronate salts and the products containing such salts are made, produced, or processed by means of a process covered by one or more claims of the '007 patent. *See* **Section VI. B.**, *infra*.

4.5 As noted, CIPLA's infringing products that have been imported into the United States include alendronate salts in tablet form. *See* **Exhibit 16**. In addition, CIPLA claims a global presence and sells its raw materials (including bulk drugs) for export. *See* **Exhibit 17a**. CIPLA's website identifies alendronate sodium as a bulk drug product available for export. *See* **Exhibit 17b**. Upon information and belief, CIPLA has agreed to supply its generic partners in the United States with bulk alendronate. *See* **Exhibit 11** at 3 and **Section VI**. Upon information and belief, at least one of CIPLA's generic partners, Teva Pharmaceuticals ("Teva"), will purchase bulk alendronate from CIPLA for importation into the United States and will be permitted by the FDA to market generic FOSAMAX® tablets containing CIPLA's alendronate

sodium beginning in February 2008. At that time, MERCK's protection and pediatric exclusivity under the basic patent on the use of alendronate, U.S. Patent No. 4,621,077 ("the '077 patent"), will expire.[7] Teva is presumably taking these steps in light of provisions contained in the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the "Hatch-Waxman Act," which allow generic drug companies to market generic versions of patented drugs immediately upon the expiration of the relevant patents. *See* **Section VI.**

V. THE PATENT AT ISSUE

A. Identification Of The Patent And Ownership By MERCK

5.1 U.S. Patent No. 4,922,007, entitled "Process for Preparing 4-Amino-1-Hydroxybutylidene-1,1-Bisphosphonic Acid or Salts Thereof," issued on May 1, 1990, to inventors Gerard R. Kieczykowski, David G. Melillo, and Ronald B. Jobson. The '007 patent is assigned to MERCK. CIPLA infringes claims 1-5 of the '007 patent.

5.2 Pursuant to Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by the following: (1) a certified copy and three additional copies of the prosecution history of the '007 patent; and (2) four copies of each reference document mentioned in the prosecution history of the patent.

B. Non-Technical Description Of The Patented Invention

5.3 The invention claimed in the '007 patent is an improved process for the preparation of the compound that yields the active pharmaceutical ingredient in MERCK's FOSAMAX® tablets, alendronate sodium.

5.4 Before the invention disclosed in the '007 patent, the preparation of alendronate was performed according to a process patented in 1983 by Henkel Kommanditgesellschaft auf

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[7] MERCK's protection and pediatric exclusivity under the basic patent on the use of alendronate, U.S. Patent No. 4,621,077 ("the '077 patent"), will expire February 6, 2008.

Aktien ("Henkel"). The process patented by Henkel, however, is cumbersome and problematic in several ways. For example, the Henkel process often results in a reaction mixture that does not remain homogeneous, leading to undesirable inconsistencies in the resulting product. The Henkel process is also plagued by localized solidification, i.e., the formation of solid chunks in the reaction mixture, or a kind of lumpiness in the reaction mixture, which leads directly to unacceptably variable yields. In addition, the use of concentrated hydrochloric acid in the Henkel process risks the release of fumes with adverse environmental and safety consequences. There is also a known exotherm in the reaction of the raw materials involved in the production of alendronate sodium by the Henkel process, which can lead to a very dangerous and unstable condition. Lastly, the Henkel process requires first the isolation of the purified bisphosphonic acid and then the conversion of the bisphosphonic acid to alendronate sodium.

5.5 The process disclosed in the '007 patent involves the production of alendronate from the reaction of 4-aminobutyric acid ("GABA") with phosphorus trichloride and phosphorous acid in the presence of methanesulfonic acid ("MSA") or an equivalent sulfonic acid. The mixture of reactants is hydrolyzed to yield a bisphosphonic acid that is converted into alendronate sodium. The alendronate sodium is then crystallized directly from the reaction mixture after quenching, hydrolysis, and pH adjustment with no further purification necessary. This direct crystallization of alendronate sodium is only possible because of the high purity of the crude drug substance obtained from this hydrolysis mixture. This results in a simplified purification procedure and the complete elimination of certain steps required by the Henkel process. These changes directly result in a more homogeneous mixture, and a more homogeneous mixture results in higher yields and an improved safety profile.

5.6 The process claimed in the '007 patent solves the problems of the Henkel process in part by allowing the reaction mixture to remain fluid and homogeneous. As the mixture remains homogeneous, no localized solidification occurs, and therefore, yield rates improve greatly. The process of the '007 patent makes the commercial manufacture of alendronate possible, while simultaneously providing for a reduction in the number of steps required,

including the complete elimination of the problematic step involving concentrated hydrochloric acid, and resulting in a dramatic increase in yield. The invention claimed in the '007 patent makes the production of alendronate cheaper, easier, safer, more consistent, and more environmentally friendly.

C. Foreign Counterparts

5.7 The foreign patents or foreign patent applications corresponding to the '007 patent are set forth in **Exhibit 18.** Upon reasonable investigation, Merck is aware of no other foreign patents or patent applications that have been issued, abandoned, denied, or remain pending.

VI. UNFAIR ACTS OF THE PROPOSED RESPONDENT

A. Importation Of Proposed Respondent's Infringing Products

6.1 Upon information and belief, CIPLA imports into the United States, sells for importation, and/or sells in the United States after importation certain alendronate salts and products containing the such salts that are made, produced, or processed by means of a process covered by the '007 patent. *See* **Exhibits 12-13.** CIPLA is not licensed under the '007 patent to make, use, sell, offer for sale, or import such alendronate salts or products containing such salts.

6.2 Upon information and belief, CIPLA does not maintain a manufacturing facility for the accused products in the United States. *See* **Exhibit 15**. **Exhibit 15** is a page from CIPLA's website that lists its manufacturing facilities, each of which is located in India. Moreover, the listed subject of CIPLA's DMF ("ALENDRONATE SODIUM TRIHYDRATE AS MANUFACTURED IN MAHARASHTRA INDIA") shows that its alendronate salts are produced in India. *See* **Exhibit 10.** MERCK is not aware of any other Indian company that has filed a DMF for alendronate sodium for the United States market.

6.3 CIPLA imports, sells for importation into the United States, or sells after importation in the United States alendronate sodium tablets – OSTEOFOS. As described in the declaration and supporting documents attached at **Exhibit 13,** OSTEOFOS was purchased in the

United States from five such Internet pharmacies: Healthy Choice Pharmacy, Freedom Pharmacy, Pharmacy Geoff, Inhouse Drugstore, and GlobalDrug.tv.

6.4 OSTEOFOS is available via the Internet through Healthy Choice Pharmacy. **Exhibit 13** at ¶¶ 3-5 and 7. Copies of the order confirmation and receipt reflecting the purchase of OSTEOFOS 70, OSTEOFOS 10, and OSTEOFOS 5 through Healthy Choice Pharmacy are attached. *See* **Exhibit 13** at Attachments A and B. Photocopies depicting the shipping labels from the packages corresponding with that purchase are also attached. *See* **Exhibit 13** at Attachments C and G. The labels in Attachment G show that at the very least the OSTEOFOS 5 tablets were shipped from Pune, India to Bombay, India (now known as Mumbai, India), and then to the United States. CIPLA manufactures alendronate in Pune, India (a city in the Maharashtra province) and is headquartered in Mumbai, India. Images showing that the OSTEOFOS purchased through Healthy Choice Pharmacy contains alendronate sodium and was manufactured by CIPLA are also attached. *See* **Exhibit 13** at Attachments D and H.

6.5 OSTEOFOS is also available via the Internet through Freedom Pharmacy. **Exhibit 13** at ¶¶ 6 and 8. Copies of the order confirmation and receipt reflecting the purchase of OSTEOFOS through Freedom Pharmacy are attached. *See* **Exhibit 13** at Attachment E and F. Photocopies depicting the shipping labels from the packages corresponding with that purchase are also attached. *See* **Exhibit 13** at Attachments I and K. A comparison of those labels with the labels accompanying the OSTEOFOS 5 shipment from Healthy Choice Pharmacy shows that the OSTEOFOS purchased through Freedom Pharmacy traveled a seemingly identical route from Pune, India to Bombay, India (now known as Mumbai, India) to the United States. The packaging materials and envelopes accompanying the shipments from Freedom Pharmacy also appear to be substantially identical to the materials and envelopes that correspond to the order placed through Healthy Choice Pharmacy. *Compare* **Exhibit 13** at Attachment G *with* **Exhibit 13** at Attachments I and K. CIPLA manufactures alendronate in Pune, India (a city in the Maharashtra province) and is headquartered in Mumbai, India. Images showing that the

OSTEOFOS purchased through Freedom Pharmacy contains alendronate sodium and was manufactured by CIPLA are also attached. *See* **Exhibit 13** at Attachments J and L.

6.6 OSTEOFOS is also available over the Internet through Pharmacy Geoff. **Exhibit 13** at ¶¶ 9-11. Copies of the order confirmation and receipt reflecting the purchase of OSTEOFOS through Pharmacy Geoff are attached. *See* **Exhibit 13** at Attachments M and N. Photocopies depicting the shipping labels from the packages corresponding with that purchase are also attached. *See* **Exhibit 13** at Attachment O. Those labels show that the OSTEOFOS tablets in question were shipped from Fiji to the United States. In addition, images showing that the OSTEOFOS purchased through Pharmacy Geoff contains alendronate sodium and was manufactured by CIPLA are attached. *See* **Exhibit 13** at Attachment P.

6.7 OSTEOFOS is also available over the Internet through Inhouse Drugstore. **Exhibit 13** at ¶¶ 12-13. Copies of the order confirmation and receipt reflecting the purchase of OSTEOFOS through Inhouse Drugstore are attached. *See* **Exhibit 13** at Attachments Q and R. Photocopies depicting the shipping labels from the packages corresponding with that purchase are also attached. *See* **Exhibit 13** at Attachments S. Those labels show that the OSTEOFOS tablets in question were shipped from Vanuatu to the United States. In addition, images showing that the OSTEOFOS purchased through Inhouse Drugstore contains alendronate sodium and was manufactured by CIPLA are attached. *See* **Exhibit 13** at Attachment T.

6.8 OSTEOFOS is also available over the Internet through GlobalDrug.tv. **Exhibit 13** at ¶¶ 14-15. Copies of the order confirmation and receipt reflecting the purchase of OSTEOFOS through GlobalDrug.tv are attached. *See* **Exhibit 13** at Attachments U and V. Photocopies depicting the shipping labels from the packages corresponding with that purchase are also attached. *See* **Exhibit 13** at Attachment W. Those labels show that the OSTEOFOS tablets in question were shipped from Vanuatu to the United States. In addition, images showing that the OSTEOFOS purchased through GlobalDrug.tv contains alendronate sodium and was manufactured by CIPLA are attached. *See* **Exhibit 13** at Attachment X.

6.9 Upon information and belief, CIPLA also has agreements to supply bulk alendronate in powder form to its generic drug company partners in the United States. *See* **Exhibit 11** at 3; **Exhibit 8** at 14. Upon further information and belief, certain of CIPLA's partners intend to formulate and/or package CIPLA's bulk alendronate into tablet form for imminent distribution in the United States. Accordingly, upon information and belief, the statements in **Exhibit 11** indicating that CIPLA would be the supplier of bulk alendronate but for the "patent holders winning their cases against CIPLA's partners," referto litigation in the United States between plaintiff MERCK and co-defendants Teva Pharmaceuticals and Zenith Goldline Pharmaceuticals regarding FOSAMAX® tablets. *See* **Section X.** During the discovery phase of that same litigation, Teva produced alendronate tablets and bulk alendronate to MERCK. Upon information and belief, CIPLA manufactured the alendronate contained in those tablets and that bulk alendronate, and then sold for importation or imported the same into the United States. *See* **Exhibits 8, 11,** and **17.**

6.10 Under the Hatch-Waxman Act, the generic drug companies with whom CIPLA has contracted will be able to market their generic alendronate sodium products in the United States beginning in February 2008. One of CIPLA's strategic alliance partners, Teva Pharmaceuticals, has declared that it will enter the alendronate market immediately in February 2008. *See* **Exhibit 19** at 15, **Exhibit 20** at 11, ¶ 74 and **Section X**. Teva Pharmaceuticals has stated that it has "made substantial preparation in the United States to import, offer to sell, and sell" alendronate tablets in the United States and that this involves a "substantial investment" on its part. **Exhibit 20** at 10, ¶70 and 13, ¶80. As **Exhibits 8** and **10** indicate, CIPLA holds a DMF for alendronate sodium. Accordingly, CIPLA is ready to supply alendronate sodium to its generic partners, including Teva Pharmaceuticals. CIPLA's importation of bulk alendronate sodium is therefore imminent.

B. Infringement

6.11 Upon information and belief, CIPLA's alendronate salts and products containing such salts are made, produced, or processed by means of a process covered by claims 1-5 of the '007 patent.

6.12 Upon information and belief, CIPLA manufactures alendronate sodium by a process that infringes claims 1-5 of the '007 patent. The factual basis supporting MERCK's belief is set forth in the accompanying report attached hereto as **Exhibit 12**. As shown in **Exhibit 12**, analysis of CIPLA's alendronate tablets proves that CIPLA's alendronate tablets contain significant amounts of sulfonic acid, and the presence of such sulfonic acid indicates that the alendronate in CIPLA's alendronate tablets was manufactured by the process claimed in MERCK's '007 patent. A claim chart reading representative claim 1 of the '007 patent on the accused process is attached hereto as **Exhibit 21**.

6.13 On April 3, 2006, MERCK contacted CIPLA requesting a copy of CIPLA's DMF file, which contains a detailed description of the process used by CIPLA to manufacture its alendronate. *See* **Exhibit 22.** CIPLA has not substantively responded to MERCK's request. Although MERCK has undertaken reasonable efforts to learn the relevant details of CIPLA's process for manufacturing alendronate, it has been unable to do so. Accordingly, pursuant to 35 U.S.C. § 295, MERCK presumes that CIPLA's alendronate is manufactured by the process claimed in the '007 patent.

VII. CLASSIFICATION OF THE INFRINGING PRODUCTS UNDER THE HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES

7.1 Upon information and belief, Proposed Respondent's infringing products may be classified under at least the following headings of the Harmonized Tariff Schedule of the United States: 3004.90.9190 and 2931.00.9030.

VIII. LICENSE

8.1 Other than internal agreements with its subsidiaries and other MERCK corporate entities, MERCK has not licensed its patents for manufacturing alendronate sodium.

IX. THE DOMESTIC INDUSTRY

9.1 As defined by Section 337(a)(2) and (a)(3), a domestic industry exists in connection with MERCK's activities related to certain alendronate salts and products containing such salts that practice claims of the '007 patent, including significant United States investments in plant and equipment, and significant employment of labor in the United States.

9.2 MERCK currently manufactures alendronate sodium, the active ingredient in MERCK's FOSAMAX® tablets at its facilities in Ballydine, Ireland. The alendronate sodium is then distributed worldwide to regional MERCK production facilities, including facilities in the United States. In these production facilities, the alendronate sodium is formulated with the inactive ingredients for processing into FOSAMAX® tablets. These tablets are then packaged for sale or sent to another facility in the United States for blistering (a particular kind of intermediate packaging step) and then final packaging. Pursuant to 19 C.F.R. § 210.12(b), **Exhibit 23** contains photocopies of MERCK's once weekly FOSAMAX® tablets.[8] **Confidential Exhibit 24** provides a detailed description of the supply chain for FOSAMAX® tablets. MERCK's facilities in the United States produce significant quantities of FOSAMAX® tablets for distribution in the United States. MERCK's net global sales of FOSAMAX® tablets totaled $3.2 billion in 2005.

A. MERCK Manufactures Products Using The Process Claimed In The '007 Patent

9.3 In manufacturing alendronate sodium, MERCK uses the process claimed in the '007 patent. Pursuant to 19 C.F.R. § 210.12(a)(9)(viii), **Confidential Exhibit 25** contains the

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8 Inasmuch as the drug FOSAMAX® is a prescription drug, it is not practicable for MERCK to provide the Commission with physical samples of FOSAMAX® tablets.

portions of the NDA submitted by MERCK to the FDA describing in detail the manufacturing process actually used by MERCK to make alendronate sodium. **Confidential Exhibit 26** is a claim chart applying claim 1 of the '007 patent to MERCK's process, as described in **Confidential Exhibit 25,** for manufacturing alendronate sodium, which is then used to produce FOSAMAX® tablets.

B. MERCK's Significant Investments In Plant And Equipment In The United States

9.4 MERCK has made significant investments in plant and equipment devoted to the production, formulation and packaging of FOSAMAX® tablets in the United States. As described above, FOSAMAX® tablets are the pharmaceutical product containing the active ingredient of alendronate sodium, which is made by the process claimed in the asserted patent.

9.5 MERCK produces FOSAMAX® tablets in the United States at its facilities in Arecibo, Puerto Rico and Wilson, North Carolina. At these facilities MERCK formulates, doses, blisters and packages FOSAMAX® tablets for distribution in the United States. **Confidential Exhibit 4** sets forth the square footage and value of MERCK's facilities that are utilized in the production of FOSAMAX® tablets.

9.6 MERCK also has made significant investments in the equipment utilized in the production of FOSAMAX® tablets. **Confidential Exhibit 5** sets forth MERCK's approximate investment in representative equipment used to produce FOSAMAX® tablets and a list of such equipment.

C. MERCK's Significant Employment Of Labor In The United States

9.7 MERCK employs a significant amount of labor in the United States to produce FOSAMAX® tablets. **Confidential Exhibit 6** identifies the number of MERCK employees involved in such production at MERCK's facilities in Puerto Rico and North Carolina.

9.8 MERCK also employs a significant amount of labor in the United States to distribute FOSAMAX® tablets. **Confidential Exhibit 6** identifies the number of employees involved in such distribution activities by MERCK.

D. MERCK's Substantial Investment In The Exploitation Of The '007 Patent

9.9 MERCK has made substantial investments in the exploitation of the '007 patent. More specifically, Merck has made substantial investments in the research and development of its patented process, and has made further substantial investments to protect the intellectual property associated with the '007 patent.

X. RELATED LITIGATION

10.1 MERCK is currently seeking a declaratory judgment of infringement of the '007 patent (along with other patents) against Teva Pharmaceuticals USA, Inc. in *MERCK & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 2:06-cv-2484 (D.N.J.) and against Barr Laboratories, Inc. in *MERCK & Co., Inc. v. Barr Laboratories, Inc.*, Civil Action No. 2:06-cv-2486 (D.N.J.). The complaints in those actions were filed on June 1, 2006. Defendant Teva filed an answer and counterclaim alleging noninfringement and invalidity of Merck's asserted patents on July 21, 2006. Defendant Barr filed an answer and counterclaim alleging noninfringement and invalidity of Merck's asserted patents on July 31, 2006.

10.2 MERCK has asserted the foreign counterparts of the '007 patent against many companies in various countries in its efforts to protect its patented process.

- Australia – *Alapharm Pty. Ltd. v. Merck & Co., Inc.*, involves a Statement of Claim filed by Alapharm against Merck in relation to MERCK's Patent No. 625704. The action is currently pending.
- Bolivia – *Merck & Co., Inc. v. Pharma Investi*, involves the alleged infringement of process claims of MERCK's Patent No. 5306B. The action is currently pending.

- Canada – In *Merck & Co., Inc. v. Novopharm Limited*, Notice of Allegation-T-2149-01, Novopharm alleged invalidity of the product claims in MERCK's Patent No. 2,018,477. The process claims were not in issue. This case has settled.

- Canada – In *Merck & Co., Inc. et al v. Apotex Inc. et al*, Notice of Allegation Court No. (T568-03), Apotex has alleged invalidity of the product claims of MERCK's Patent No. 2,018,477. The process claims are not in issue. This case is pending.

- Canada – In *Merck & Co., Inc. And Merck Frosst Canada & Co. v. Brantford Chemicals Inc*, Court File No. T-1780-03, Merck filed action for infringement of the process claims of the MERCK's Patent No. 2,018,477. This case is pending.

- Canada - *Merck & Co., Inc. And Merck Frosst Canada & Co. v. Novopharm Limited*, Court File No. T-1778-03, Merck filed action for infringement of the process claims of the MERCK's Patent No. 2,018,477. This case is pending.

- Denmark – *Ratiopharm v. Merck & Co., Inc.*, Ratiopharm challenged the product claims of MERCK's Patent No. 402152. Merck submitted the patent for reexamination in the Danish Patent Office. The case is stayed pending resolution of the reexamination.

- France – *Arrow and EG Labo Eurogenerics v. Merck & Co. and MSD-Somerset Ltd.*, involves the product claims of MERCK's Patent No. 402152. The process claims of that patent are not at issue.

- Honduras – *Anaprohfar v. Merck & Co., Inc.*, involves MERCK's Patent No. 3650. The product claims have been invalidated. The process claims of that patent are not at issue. This case is on appeal.

- Hungary – *Merck & Co., Inc. v. Richter Gedeon*, involves the product claims of MERCK's Patent No. 211,908. The process claims of that patent were not at issue. The product claims were revoked by the Hungarian Patent Office, and the action has been terminated.

- Israel – *Merck & Co., Inc. & Merck, Sharp and Dohme (Israel – 1996) Ltd. v. Unipharm Ltd., Zvulun Tomer, & Tarima Israel Medical Products Maabarot Ltd*, Case No. Civil 002085/00, involves the alleged infringement of MERCK's Patent No. 94612. The lower court did not reach the substantive issues of the process claims involved in this litigation because of a finding against MERCK on other issues. This case is currently on appeal.

- Korea – *Merck & Co., Inc. v. Yu Yu Industry Co., Ltd*, Case No. 98-KaHap-728, involves the alleged infringement of Korean Patent Registration No. 137455. The Korean Intellectual Property Office revoked the product claims of this patent. This revocation was later reversed. The case was terminated pending further prosecution of the product claims.

- Korea – *Merck & Co., Inc. v. Hwan In Pharmaceuticals Co., Ltd*, Case No. 98-KaHap-2330, involves the alleged infringement of Korean Patent Registration No. 137455. The Korean Intellectual Property Office revoked the product claims of this patent. This revocation was later reversed. The case was terminated pending further prosecution of the product claims.

- Portugal – *Merck & Co., Inc et al. v. Tecnimede – Soc. Tecnico-Medicinal, S.A*, Case No. 217/2001, involves the alleged infringement of MERCK's Patent No. 94306. The Court denied MERCK's request for a preliminary injunction based upon the product claims. This ruling is on appeal. The main action is still pending.

- Portugal – *Merck & Co., Inc et al. v. Farmoz*, involves the alleged infringement of MERCK's Patent No. 94306. The Court denied MERCK's request for a preliminary injunction based upon the product claims. This ruling is on appeal. The main action is still pending.

- Portugal – In *Tecnimede – Soc. Tecnico-Medicinal, S.A. v. Merck & Co., Inc.*, Case No. 317/2002, Plaintiff asserted that the product claims of MERCK's Patent No. 94306 were invalid. The process claims were not at issue. This case is still pending.

- Romania – *Gedeon Richter v. Merck & Co., Inc.*, involved the product claims of MERCK's Patent No. 402152. The product claims were upheld, and the process claims were not at issue. This case has been terminated.

- United Kingdom - The case, *Merck & Co., Inc. v. Arrow Generics (UK) Limited*, Case No. HC 02 C 00845, involved the alleged infringement of MERCK's Patent No. 402152 B1, but the process claims of that patent were not at issue. This case has been terminated.

- United Kingdom - The case, *Merck & Co., Inc. v. Arrow Generics (UK) Limited*, Case No. HC 02 C 01761, involved the alleged infringement of MERCK's Patent No. 402152 B1, but the process claims of that patent were not at issue. This case has been terminated.

- United Kingdom - The case, *Merck & Co., Inc. v. Generics (UK) Limited*, Case No. HC 03 C 02266, involved the alleged infringement of process claims of MERCK's Patent No. 402152 B1. The court found that MERCK's patent was not infringed.

Upon reasonable investigation, Merck is aware of no other foreign court proceedings involving foreign counterparts to the '007 patent.

10.3 MERCK has asserted U.S. Patent Nos. 4,621,077 and 5,994,329, which are the basic and the method of dosing patents for FOSAMAX® tablets, against several generic drug manufacturers, including the following:

- *MERCK & Co., Inc. v. Teva Pharmaceuticals USA, Inc., and Zenith Goldline Pharmaceuticals, Inc.*, Civil Action Nos. 00-035 and 00-052 (JJF) (D. Del.): The district court found that the defendants' ANDA for a generic version of FOSAMAX® tablets literally infringed claim 1 of MERCK's U.S. Patent No. 4,621,077 and that the asserted patent claim was valid. *See* 228 F. Supp. 2d 480 (D. Del. 2002). This finding has been affirmed by the Federal Circuit. *See* 347 F. 3d 1367 (Fed. Cir. 2003).

- *MERCK & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 01-048 (JJF) (D. Del.): Teva stipulated to infringement of certain claims of U.S. Patent No. 5,994,329, if the patent claims were found valid. The asserted patent claims were found valid by the district court . *See* 288 F. Supp. 2d 601 (D. Del. 2003). The Federal Circuit found the patent claims to be invalid and reversed the finding of the district court. *See* 395 F.3d 1364 (Fed. Cir. 2005).

- *MERCK & Co., Inc. v. Barr Laboratories, Inc.*, Civil Action No. 01-CV-8223 (S.D.N.Y.): On August 31, 2001, MERCK filed a complaint seeking a declaratory judgment of infringement of U.S. Patent No. 5,994,329. Barr agreed to be bound by the Delaware District Court's decision in the *MERCK v. Teva* case involving the same patent.

10.4 Pursuant to Commission Rule 210.12(a)(5), there has been no other court or agency litigation, foreign or domestic, involving the unfair acts that are the subject matter of this Complaint.

XI. RELIEF REQUESTED

11.1 WHEREFORE, by reason of the foregoing, Complainant MERCK respectfully requests that the United States International Trade Commission:

(a) Immediately institute an investigation pursuant to 19 U.S.C. § 1337(b)(1) into the violations of that section based on Proposed Respondent's unlawful importation into the United States, sale for importation into the United States, or sale within the United States after importation of certain alendronate salts and any products containing same, including bulk alendronate sodium or alendronate sodium tablets that are made,

produced, or processed by means of a process that infringes one or more claims of U.S. Patent No. 4,922,007;

(b) Issue a permanent limited exclusion order pursuant to 19 U.S.C. § 1337(d)(2), prohibiting from entry into the United States of Proposed Respondent's alendronate salts and products containing same, including bulk alendronate sodium and alendronate sodium tablets that are imported into the United States, sold for importation into the United States, or sold within the United States after importation and that are made, produced, or processed by means of a process that infringes one or more claims of U.S. Patent No. 4,922,007;

(c) Issue a permanent cease and desist order pursuant to 19 U.S.C. § 1337(f), prohibiting Proposed Respondent, its affiliates, subsidiaries, successors, or assigns from marketing, demonstrating, distributing, offering for sale, selling, or otherwise transferring, including the movement or shipment of inventory, in the United States, any imported alendronate salts or products containing same that infringe one or more claims of United States Patent No. 4,922,007; and

(d) Grant such other and further relief as the Commission deems appropriate and just under the law, based on the facts complained of herein and determined by the investigation.

Respectfully submitted,

Date: August 22, 2006

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VERIFICATION OF COMPLAINT

I, Louise Park Stejbach, declare, in accordance with 19 C.F.R. §§ 210.4 and 210.12(a), under penalty of perjury, that the following statements are true.

1. I am Vice President, Osteoporosis Marketing, of Complainant MERCK & CO., INC., and am duly authorized to sign this Complaint on behalf of Complainant.

2. I have read the foregoing Complaint. To the best of my knowledge, information, and belief, formed after an inquiry reasonable under the circumstances:

3. The foregoing Complaint is well founded in fact and is warranted by existing law or by a non-frivolous argument for the extension, modification, or reversal of existing law or the establishment of new law;

4. The allegations and other factual contentions have evidentiary support or are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery; and

5. The foregoing Complaint is not being filed for an improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of the investigation or related proceeding.

Executed this 16th day of August, 2006.